510(k) Summary

Cayenne Medical, Inc.

LabraLink™ Suture Anchor

510(k) Number: **K112960**

ADMINISTRATIVE INFORMATION

Manufacturer Name:
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FAX (480) 502-3670

Official Contact:
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DEVICE NAME

Classification Names: Smooth or threaded metallic bone fixation fastener

Trade/Proprietary Name: LabraLink™ Suture Anchor

Common Name: Suture Anchor

DEVICE CLASSIFICATION

FDA has classified bone screws as Class II devices (21 CFR 888.3040). The product code for screw, fixation, bone is MBI. These devices are reviewed by the Orthopedic Joint Devices Branch.

INTENDED USE

The Cayenne Medical, Inc. LabraLink™ Suture Anchor is intended for the reattachment of soft tissue to bone for shoulder procedures such as Bankart repair and SLAP lesion repair.

DEVICE DESCRIPTION

The LabraLink™ Suture Anchor is a sterile, manually operated, single procedure suture anchor device for reattachment of soft tissue to bone for shoulder procedures such as Bankart repair and SLAP lesion repair. The anchor has two suture eyelets allowing for one or two sutures to be loaded through the eyelets. The suture anchor is mounted on an inserter. The LabraLink Suture Anchor incorporates design features that facilitate suture anchor placement under arthroscopic, open, or limited access conditions in soft tissue to bone for shoulder procedures such as Bankart repair and SLAP lesion repair.

The LabraLink Suture Anchor is offered in one size, 2.9 x 15 mm with four suture color options. The anchors are offered in two configurations, single loaded or double loaded sutures. Suture(s) used on the anchor are size # 2 non-absorbable surgical sutures. The LabraLink inserter has a working length of 25.8 cm with an outer shaft diameter of 3.2 mm.

Mechanical testing was performed on the LabraLink Suture Anchor and a predicate device. Testing showed ultimate pull-out strength was significantly higher than the predicate device.

EQUIVALENCE TO MARKETED PRODUCT

Cayenne Medical, Inc. demonstrated that, for the purposes of FDA's regulation of medical devices, the LabraLink™ Suture Anchor is substantially equivalent in indication and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices: Smith & Nephew BIORAPTOR 2.3 PK Suture Anchor (K071586), Force Fiber Blue Co-Braid Polyethylene non-absorbable surgical suture (K040472), Force Fiber Black Co-Braid Polyethylene non-absorbable surgical suture (K070673), Force Fiber Green Co-Braid Polyethylene non-absorbable surgical suture (K100506), and Force Fiber Blue Polyethylene non-absorbable surgical suture (K092533).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cayenne Medical, Inc.
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Scottsdale, AZ 85260

JAN - 9 2012

Re: K112960
Trade/Device Name: LabraLink™ Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 26, 2011
Received: December 28, 2011

Dear Mr. Shahriari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112960 (pg 1/1)

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112960